Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *Stephen.Ripley@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

This public meeting is intended to satisfy a commitment included in PDUFA VI. This PDUFA reauthorization is part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017. The complete set of performance goals and procedures documented in the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022 (Goals Letter) is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.* These goals were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders as part of negotiations with industry. Section I.J.2 of the Goals Letter, ''Enhancing Benefit-Risk Assessment in Regulatory Decision-Making,'' outlines the commitment for FDA to convene and/or participate in a public meeting to gather stakeholder input on key topics relating to FDA's benefit-risk assessment.

## II. Topics for Discussion at the Public Meeting

This meeting will provide FDA the opportunity to gather input from stakeholders on their experiences and perspectives regarding FDA's benefit-risk assessment. Input from this meeting will support development of the draft guidance on benefit-risk assessment for new drugs and biologics as outlined in Section I.J.2 of the Goals Letter, which FDA intends to issue by the end of June 2020. The meeting will allow participants (including industry, patients, researchers, and other stakeholders) to provide input on key topics, including the application of FDA's Benefit-Risk Framework throughout the human drug lifecycle and information that sponsors may develop or collect at the various stages of drug development that can inform the benefit-risk assessment and related regulatory decisions. This includes consideration of how relevant patient experience data and related information may inform the benefit-risk assessment. In addition, the meeting will consider appropriate approaches to communicate to the public FDA's thinking regarding a product's benefit-risk assessment.

For more information on meeting topics and discussion questions, visit *https://healthpolicy.duke.edu/events/benefit-risk-framework-public-workshop.* FDA will publish a background document outlining the topic areas that FDA plans to address in the draft guidance to this site approximately 2 weeks before the meeting date. FDA will also post the agenda and other meeting materials to this site approximately 5 business days before the meeting.

The format of the meeting will consist of a series of presentations, panel discussions, and audience Q&As. In addition to input generated through this public meeting, FDA is interested in receiving input on the planned draft guidance through written comments, which can be submitted to the public docket (see **ADDRESSES**).

## III. Participating in the Public Meeting

*Registration:* To register for the public meeting, please visit the following website: *https://events.r20.constantcontact.com/register/eventReg?oeidk=a07eg01qxxd45281872&oseq=&c=&ch.* Please register by May 10, 2019. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by May 10, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Graham Thompson no later than May 10, 2019, 11:59 p.m. Eastern Time.

*Open Public Comment:* There will be time allotted during the meeting for open public comment. Sign-up for this session will be on a first-come, first-served basis on the day of the meeting. Individuals and organizations with common interests are urged to consolidate or coordinate and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

*Streaming Webcast of the Public Meeting:* This public meeting will also be webcast. Please register for the webcast by visiting *https://events.r20.constantcontact.com/register/eventReg?oeidk=a07eg01qxxd45281872&oseq=&c=&ch.*

FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It also may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: April 18, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–08219 Filed 4–23–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Notice of a Supplemental Award to the Emergency Medical Services for Children Innovation and Improvement Center at the Baylor College of Medicine

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice of a supplemental award to the Emergency Medical Services for Children Innovation and Improvement Center at the Baylor College of Medicine—Grant Number U07MC29829.

**SUMMARY:** HRSA announces the award of a supplement for $500,000 to the Emergency Medical Services for Children (EMSC) Innovation and Improvement Center. The supplement will permit the Baylor College of Medicine, the cooperative agreement recipient, to establish and lead a new

Quality Improvement Collaborative to support the EMSC State Partnership Program during the budget period of 07/1/2018–06/30/2019. EMSC plans to increase the proportion of EMS agencies that have a designated individual responsible for the coordination of pediatric emergency care by 2020 to 30 percent.

**SUPPLEMENTARY INFORMATION:**

*Intended Recipient of the Award:* Baylor College of Medicine.

*Amount of Non-Competitive Award:* $500,000.

*Period of Supplemental Funding:* 07/01/2018–06/30/2019.

*CFDA Number:* 93.127.

*Authority:* Public Health Service Act, Title XIX, Section 1910 (42 U.S.C. 300w–9); as amended by the Emergency Medical Services for Children Reauthorization Act of 2014, Public Law 113–180.

*Justification:* Baylor College of Medicine's EMSC Innovation and Improvement Center (EIIC) provides technical assistance to State Partnership grantees on effective methods to improve EMS for pediatric patients within state and local EMS systems. Participant states will be supported by the EIIC through targeted technical assistance, the provision of tools and resources to support local efforts, and sharing of best practices. The EIIC will support the awarded states in participation in the following activities:

—Convene up to 10 state project teams awarded by HRSA comprised of the state EMSC manager and their state and local partners for one face-to-face meeting and regular virtual meetings.

—Facilitate the development of a collective action plan representing the common methods and aims across the QI collaborative for outreach to EMS agencies.

—Provide a venue for participating states to share lessons learned and best practices in outreach design and implementation.

—Provide access to subject matter expertise to advise the QI collaborative on pediatric emergency care coordination in the pre-hospital EMS setting.

—Provide technical assistance to up to 10 participating states as they implement the action plan designed through the QI collaborative.

—Facilitate an assessment at the end of the project to determine the number of EMS agencies that newly report having an individual responsible for coordinating pediatric emergency care.

**FOR FURTHER INFORMATION CONTACT:** Theresa Morrison-Quinata, Division of Child, Adolescent and Family Health, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N54, Rockville, MD 20852, Phone: 301–443–1527, Email: *TMorrison-Quinata@hrsa.gov*.

| Grantee/organization name | Grant No. | State | FY 2018 authorized funding level | FY 2018 estimated supplemental funding |
|---|---|---|---|---|
| Baylor College of Medicine | U07MC29829 | TX | $1,500,000 | $500,000 |

Dated: April 18, 2019.

**George Sigounas,**

*Administrator.*

[FR Doc. 2019–08257 Filed 4–23–19; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier OS–0990-new]**

## Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before May 24, 2019.

**ADDRESSES:** Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Cross-site Study Data for Improving Implementation Evaluation among Office of Adolescent Health (OAH) TPP Grantees to inform National Implementations (IMAGIN).

*Type of Collection:* New.

*OMB No.:* 0990–NEW–Office of Adolescent Health—OASH—OS.

*Abstract:* The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting 3 years of approval by OMB on a new collection. The IMAGIN Cross-Site Study will examine the process that federal grantees follow to get their programs and staff ready for full implementation by exploring specific factors related to the program models' readiness for implementation and evaluation, the grantee organizations' capacity to operate and deliver the program as intended, and the local enabling context. The data from this study will be used to identify meaningful lessons, targeted resources, and timely guidance that could help both current and future federal grantees get their programs ready to implement, and add to the evidence on the successes and challenges of implementing a program. The cross-site study will be conducted with leadership, key program staff and community stakeholders from Fiscal Year 2018 and, if awarded Fiscal Year 2019, grantees of the OAH Teen Pregnancy Prevention Program. It will include semi-structured interviews with grantee leadership, site visits that will include in-person discussions with key program staff and community stakeholders, and a front-line staff web survey with up to 8 front line staff per grantee.